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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**
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9 Rustom Ali,

10 Plaintiff,

11 v.

12 United States Department of Health and
13 Human Services, et al.,

14 Defendants.

No. CV-20-00310-PHX-DLR

ORDER

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16 Before the Court is Defendants' motion to dismiss, which is fully briefed. (Docs.
17 28, 35, 36.) For the following reasons, the Court will grant Defendants' motion.

18 Plaintiff Rustom Ali is the owner of several clinical laboratories in Arizona,
19 including Sonali Diagnostic Laboratory ("Sonali") in Lake Havasu. Clinical laboratories
20 must be certified under and maintain compliance with the Clinical Laboratory
21 Improvement Amendments of 1988 ("CLIA"). 42 U.S.C. § 263a(b). During a CLIA
22 survey of Sonali on January 25, 2001, the Department of Health & Human Services
23 ("HHS") documented several CLIA violations. (Doc. 25-4 at 2.) Plaintiff failed to correct
24 seven deficiencies, so HHS referred the case to the Centers for Medicare & Medicaid
25 Services ("CMS"), which levied sanctions, including revoking Sonali's CLIA certification
26 and imposing a \$30,000 penalty. (*Id.*) Plaintiff and Sonali requested a hearing before an
27 ALJ, who upheld CMS's sanctions, and the Departmental Appeal's Board ("DAB")
28 affirmed. *Sonali Diagnostic Lab.*, 2006 WL 321177, at *2, DAB 2008 (H.H.S. Jan. 17,

1 2006). Plaintiff filed a petition for review with the Ninth Circuit, which upheld the DAB's
2 decision. *Ali v. U.S. Dept. of Health and Human Serv.*, 240 F. App'x. 211 (9th Cir. 2007).
3 The Supreme Court denied Plaintiff's petition for a writ of certiorari. 55 U.S. 924 (2008).

4 On April 17, 2013, a state agency working with CMS received a new application
5 for Sonali CLIA certification from Plaintiff. (Doc. 25-3 at 1.) On April 23, 2013, CMS
6 sent Plaintiff a letter informing him that his CLIA application could not be processed
7 because, among other issues, the \$30,000 penalty remained unpaid. (*Id.*) On December
8 19, 2014, Plaintiff requested a hearing before an ALJ, but the ALJ found jurisdiction absent
9 because the correspondence from CMS—indicating that it could not process his application
10 until outstanding sanctions issue were resolved—did not constitute an initial determination
11 subject to review. *Mohave Clinical Lab/Rustom Ali, Ph.D.*, 2015 WL 6664807 (H.H.S.
12 Oct. 14, 2015). Without submitting the \$30,000 payment or resolving the other sanctions
13 issues, Plaintiff filed additional inquiries, as recently as January 8, 2020, requesting that
14 Sonali be issued a CLIA certificate. (Docs. 25-6, 25-8.) CMS repeatedly explained to
15 Plaintiff that it found no legal or factual basis to issue a CLIA certificate to Sonali or to
16 change its position. (Docs. 25-5; 25-6.)

17 On February 11, 2020, Plaintiff filed suit in this Court, seeking Sonali's readmission
18 to the CLIA program and reissuance of its CLIA certificate of compliance, despite his
19 failure to cure the sanctions issues, which he continues to contend are invalid.¹ (Doc. 1.)
20 Plaintiff amended his complaint on April 8, 2020. (Doc. 25.) Defendants moved to dismiss
21 on April 27, 2020, making various arguments to address claims that they believed Plaintiff
22 raised in his muddled amended complaint. (Doc. 28.) Plaintiff clarified in response to
23 Defendants' motion that "[P]laintiff raised only one cognizable legal claim: Reinstatement
24 into CLIA program and reissuance of CLIA license of certification of compliance
25 (Reinstatement)." (Doc. 35 at 2.)

26 "A federal court is presumed to lack jurisdiction in a particular case unless the

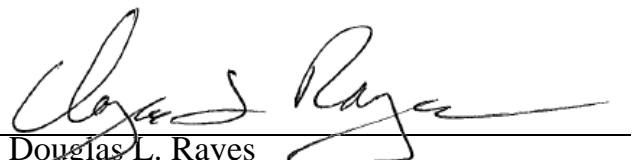
27 ¹ Notably, the Court terminated Sonali as a plaintiff in this matter due to its failure
28 to secure representation. (Doc. 24.) Plaintiff may not bring claims on Sonali's behalf.
Although not a basis for Defendants' motion to dismiss, this flaw in Plaintiff's case, alone,
is fatal.

1 contrary affirmatively appears.” *Stock West, Inc. v. Confederated Tribes of the Colville*
2 *Reservation*, 873 F.3d 1221, 1225 (9th Cir. 1989) (citation omitted). Plaintiff bears the
3 burden of establishing jurisdiction. Plaintiff has not met this burden.

4 CLIA expressly provides for review of the denial of CLIA certificates through an
5 administrative process and then by a federal circuit court. 42 U.S.C. § 263a(k). Although
6 Plaintiff attempts to distance himself from these requirements by arguing that Sonali is not
7 applying for an entirely new CLIA certification, but rather for a reissuance of its old
8 certification, this distinction is based in neither law nor fact. CMS did not merely
9 temporarily suspend Sonali’s certification, it revoked it. Sonali is not renewing its
10 certification; it is applying anew. Meaning, CLIA regulations concerning the denial of new
11 CLIA certificates apply. Within this CLIA framework, Plaintiff has failed to establish
12 jurisdiction. Even if Plaintiff had shown that he exhausted his administrative remedies
13 here, which he has not, the district court is not the proper court to handle CLIA appeals.
14 Accordingly,

15 **IT IS ORDERED** that Defendants’ motion to dismiss (Doc. 28) is **GRANTED**.
16 Plaintiff’s complaint is dismissed. The Clerk of Court is directed to terminate the case.

17 Dated this 23rd day of June, 2020.

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22 Douglas L. Rayes
23 United States District Judge
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